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DEVELOPMENT OF A PREDICTION METHOD FOR SOUND CONDUCTION EFFICIENCY OF THE HUMAN MIDDLE EAR – APPLICATION TO TYPE Ⅳ OPERATION –

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Key words: Geometric Model, FEM, Vibration Analysis, Human Middle Ear, Auditory Ossicles, Hearing Ability.

Abstract. When the human middle ear is damaged by various ear diseases, the linkage of the auditory ossicles may be reconstructed using the column article called the columella. In a tympanoplasty operation, the sound conduction efficiency changes according to differences in shape, material and the mounting position of the columella. We have proposed a new method for estimating the hearing restoration effect prior to the operation. In this method, a geometric model of the middle ear is constructed using SolidWorks based on CT scanning data. Frequency response characteristics of the stapes displacement in sound conduction are calculated using harmonic vibration analysis. The hearing restoration effect can be estimated by a comparison of differences in the stapes displacement between the reconstruction model and a healthy subject. In the case in which the stapes remains in a normal shape, including the horseshoe portion, the type III operation is performed. In the case in which only the basal plane of the stapes is left, the type IV operation is performed. With the type IV operation, it is more difficult to improve hearing ability than with the type III operation. In the type III model, various verifications have been carried out on the validity of our prediction method. In this study, the validity of our method is verified for the type IV model. On the other hand, the audiogram is made by precise audiometry in the medical field. The audiogram is the record of the value of hearing level at every frequency in the hearing test. Using our proposed calculation formula, the audiogram of the type IV operation model was made. The degree of hearing amelioration can also be evaluated quantitatively in the type IV model prior to an operation. Through this study, the optimization of reconstruction of the middle ear using the columella becomes possible.

1 INTRODUCTION

The human auditory organ is composed of the external, middle and inner ears. The sound collected in the pinna is transmitted to the tympanic membrane through the ear canal. The acoustic wave vibration which the tympanic membrane receives is transmitted to auditory ossicles. The stapes vibration is transmitted to the labyrinthine fluid in the cochlea where electrical signals are generated. Finally, it is recognized in the brain as sound.

When the middle ear is damaged by various ear diseases, the linkage of the auditory ossicles is reconstructed using a medical device called a columella. This is called 'tympanoplasty' or auditory ossicles reconstructive surgery. In this operation, the sound conduction efficiency changes due to the difference between shape, material and the mounting position of the columella. Actually, the operation is carried out based on workmanship and experience of the doctor.

In our previous research [1,2,3], a geometric model of the middle ear on the basis of the computerized tomography (CT) scan data was constructed. Several kinds of tympanoplasty models for a middle ear damaged by chronic otitis media have been constructed and analyzed. Frequency response characteristics of the stapes displacement in sound conduction are clarified using three-dimensional finite element harmonic vibration analysis. Based on our previous research, we have proposed that the hearing restoration effect can be estimated by a comparison of the stapes displacement with the result for a healthy subject as a standard, prior to the operation.

In the case in which the stapes remains in a normal shape, including the horseshoe, the type Ⅲ operation is performed [4]. In the case in which only the basal plane of the stapes is left, the type Ⅳ operation is performed [4]. With the type IV operation, it is more difficult to improve hearing ability than with the type Ⅲ operation. In the type Ⅲ model, various verifications have been carried out on the validity of our prediction method. In this study, the validity of our method is verified for the type IV model.

In this research, the harmonic vibration analysis result of a healthy subject is shown at first. Next, the case in which a column article of the columella is substituted for the deficient auditory ossicles is analysed. The results for type Ⅲ and type Ⅳ operation models in which mounting positions of the columella are umbilical and intermediate parts of the malleus are shown. Furthermore, the correlation of hearing restoration effect and the columella volume is examined in the type Ⅳ operation model.

In the medical field, the audiogram is made by precise audiometry, and the degree of improvement of hearing ability is evaluated in pre- and post-operation. The audiogram is the record of the value of hearing level or minimum audible threshold at every frequency in the hearing test. A calculation formula which is able to obtain hearing level from the stapes displacement using the finite element analysis was devised. The degree of hearing amelioration can be evaluated quantitatively by this formula. In this study, our proposed method is applied to the type IV operation models, and its validity is discussed. Through this study, the optimization of reconstruction of the middle ear using the columella becomes possible. Finally, the efficacy of predicting the hearing restoration effect prior to an operation is clarified.

2 EAR STRUCTURE AND FUNCTIONS

The ear is the organ that controls the sense of hearing and human body balance. The ear is composed of external, middle and inner parts as shown in Figure 1. The external ear is composed of the pinna, ear canal and tympanic membrane. The function of the pinna is to collect sonic reflections, and the function of the ear canal is as a resonance tube.

The middle ear as shown in Figure 2 is composed of auditory ossicles and the auditory tube which connects with the hole of the nose. Auditory ossicles behind the tympanic membrane are in a small space (tympanic cavity) filled with air, and they connect the tympanic membrane with the cochlea of the inner ear. The vibration of the tympanic membrane is amplified by the auditory ossicles and transmitted to the inner ear.

The inner ear is composed of the cochlea and semicircular canal. In the inner ear, the vibration induced by auditory ossicles is transmitted to the labyrinthine fluid which converts it to electric signals. Finally, it is recognized in the brain as sound.

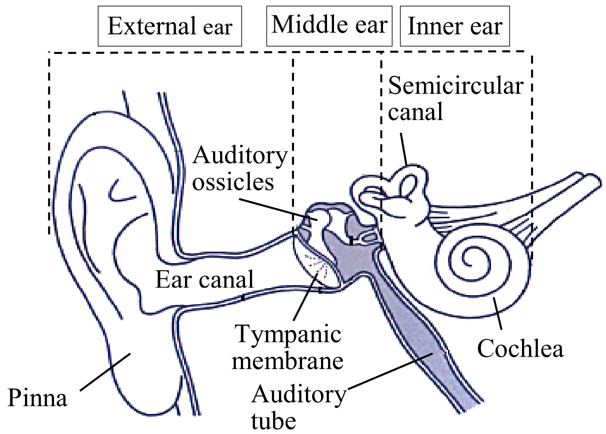


Figure 1: Ear structure

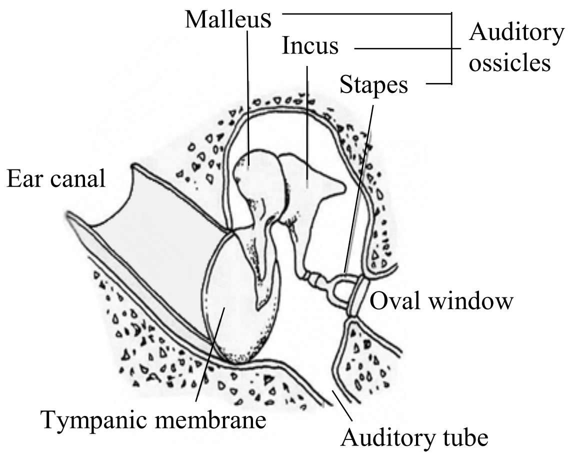


Figure 2: Middle ear structure

3 HARMONIC VIBRATION ANALYSIS OF THE MIDDLE EAR

3.1 Geometric model of a healthy subject

The geometric model for a healthy subject for finite element harmonic vibration analysis is shown in Figure 3. This model is composed of the tympanic membrane, auditory ossicles, ligaments, joints, stapedial muscle and others. These parts’ names are shown in Table 1. In order to construct a geometric model, the region which contains those ear parts was separated from the CT scanning data of the human head. These CT scanning data were converted to DICOM data, and in addition, converted into STL data which were imported into SolidWorks.

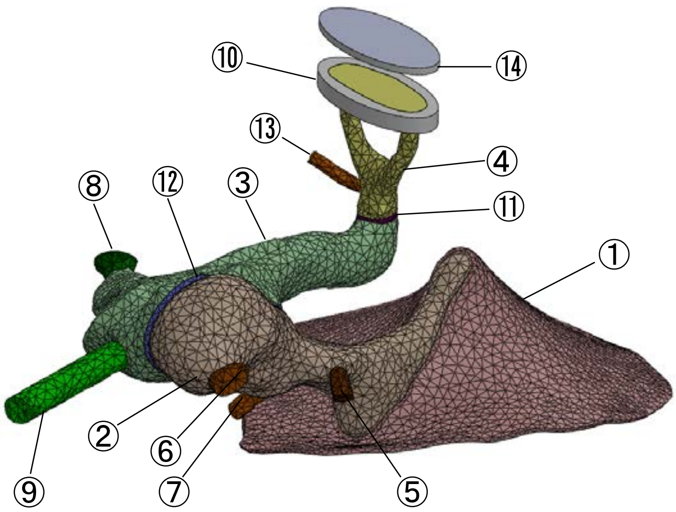


Figure 3: Geometric model of the middle ear

Table 1: Material data

<table>
<tr><th>Anatomical parts’ name</th><th>Young's Modulus [MPa]</th><th>Density [kg/m^3]</th><th>Poisson's ratio</th></tr>
<tr><td>①Tympanic membrane</td><td>33.4</td><td>1,200</td><td rowspan="14">0.3</td></tr>
<tr><td>②Malleus</td><td rowspan="3">13,436</td><td rowspan="3">4,350</td></tr>
<tr><td>③Incus</td></tr>
<tr><td>④Stapes</td></tr>
<tr><td>⑤Lateral mallear ligament</td><td rowspan="3">21</td><td rowspan="6">2,500</td></tr>
<tr><td>⑥Superior mallear ligament</td></tr>
<tr><td>⑦Anterior mallear ligament</td></tr>
<tr><td>⑧Posterior incudal ligament</td><td rowspan="3">0.65</td></tr>
<tr><td>⑨Superior incudal ligament</td></tr>
<tr><td>⑩Stapedial annular ligament</td></tr>
<tr><td>⑪Incudostapedial joint</td><td rowspan="2">6</td><td rowspan="2">1,200</td></tr>
<tr><td>⑫Incudomalleolar joint</td></tr>
<tr><td>⑬Stapedial muscle</td><td>0.52</td><td>2,500</td></tr>
<tr><td>⑭Base plate</td><td>1×10^{10}</td><td>-</td></tr>
</table>

3.2 Materia data

Material data of the analysis model are shown in Table 1 [5,6,7]. The anatomical parts' number in the table corresponds to the number in Figure 3. The base plate ⑭ is a virtual part for supporting the spring which simulates cochlea labyrinthine fluid. Therefore, its Young's modulus can be assumed to be that of a rigid body.

3.3 Boundary conditions

The circumference of tympanic membrane, edges of ligament and muscle, and base plate were perfectly fixed in constraint conditions. A sound pressure of 90dB was converted into pressure using the equation (1) as load conditions.

$$L_p = 20 \log_{10}(p / p_0) \tag{1}$$

In equation (1), $L_p = 90$ dB is the setting sound pressure (a relative noisy level) and $P_0 = 20 \times 10^{-6}$ Pa is a standard value (the lowest value of the sound intensity which is audible for humans). As a result, a pressure of $P = 0.632$ Pa was obtained. However, in this analysis, $P = 15.2$ Pa was given at the contact surface of the tympanic membrane and malleus. The ratio 15.2/0.632 equals the ratio of the total area of the tympanic membrane to the contact surface area of the tympanic membrane and malleus. A spring of 40N/m spring constant was installed between the stapes and the base plate referring to the research of Gan et al [8]. Rayleigh damping was assumed and damping factors of $\alpha = 0$ s^{-1} and $\beta = 7.5 \times 10^{-5}$s were adopted.

3.4 Finite element analysis results

In this research, harmonic vibration analysis was performed as a dynamic analysis using the finite element method. Figure 4 shows the harmonic vibration analysis results for a healthy subject. The longitudinal axis shows the average displacement of the stapes bottom in a perpendicular direction to the basal plane, and the lateral axis represents the frequency. The average displacement of the stapes base for the sound pressure of 90dB is 5.0×10^{-6} mm, which was used as a standard value in this model. In the case where the medical device, called the columella, is substituted for the deficient auditory ossicles, if the stapes displacement is compared with that of a healthy subject, the hearing restoration effect can be estimated,

An example of the type Ⅲ tympanoplasty model [4] is shown in Figure 5. Figure 5 (a) shows the model in which the columella is attached at the umbilical region, that is, the tip of the malleus. Its analysis result of the frequency response graph of the stapes bottom is shown in Figure 4. The value of the maximum displacement is 4.7 nm at about 1.5 kHz of frequency. This displacement of 4.7 nm is about 94% of the healthy subject. This means that hearing ability recovers to a normal level. For another example, the model in which the columella is attached at the intermediate region, that is, between the tip of the malleus and the short process of the malleus, is shown in Figure 5 (b). Analysis results are shown in Figure 4. In this case, the value of the maximum displacement is 4.4 nm which is about 88% for the healthy subject. This means that hearing ability recovers to an almost normal level.

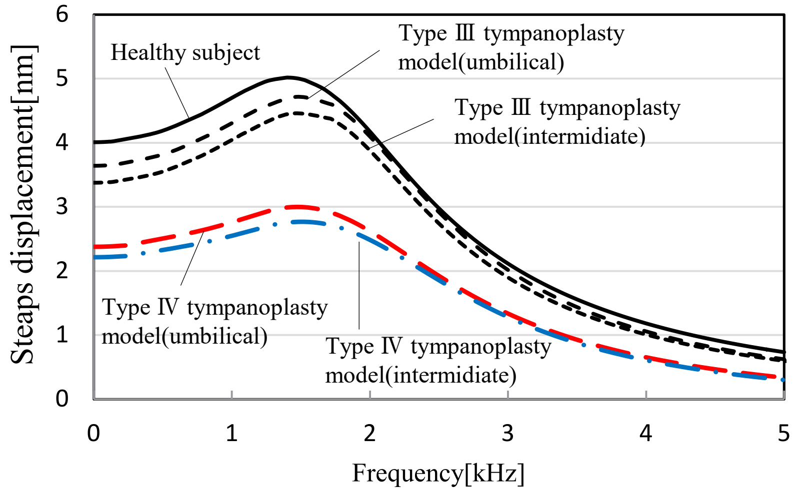
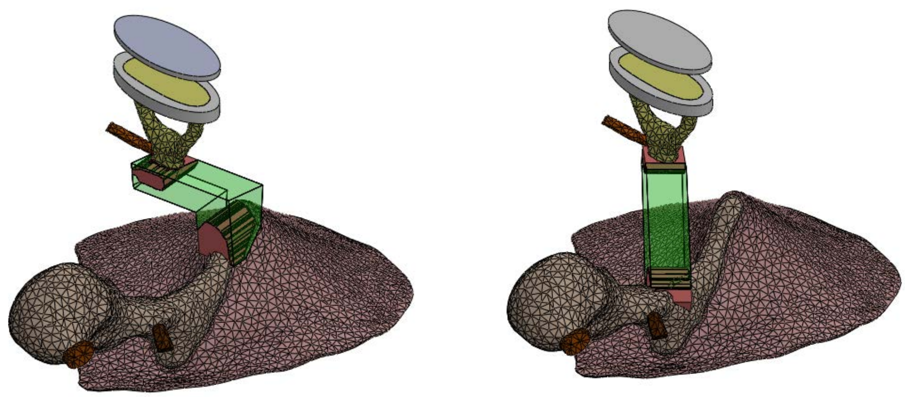


Figure 4: Frequency response graphs of a healthy subject and the tympanoplasty models



(a) Umbilical connection model (b) Intermediate connection model

Figure 5: Examples of the type Ⅲ tympanoplasty model

(a) Umbilical connection model (b) Intermediate connection model

Figure 6: Example of the type Ⅳ tympanoplasty model

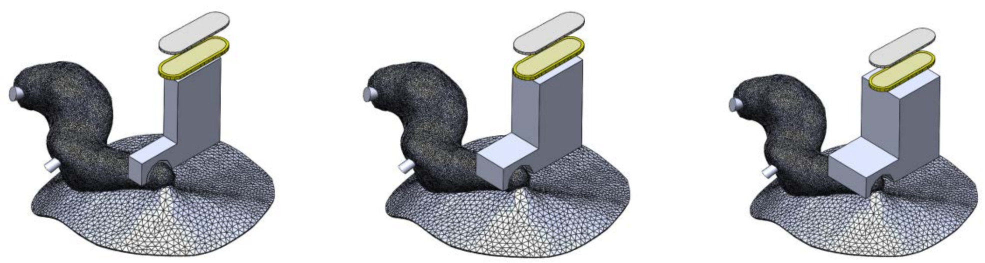
An example of the type Ⅳ tympanoplasty model [4] is shown in Figure 6. Figure 6 (a) shows the model in which the columella is attached at the umbilical region. The analysis result of the frequency response graph of the stapes bottom is shown in Figure 4. The value of the maximum displacement is 3.01 nm at about 1.5 kHz of frequency. This displacement of 3.01 nm is about 60% of the healthy subject. This means that hearing ability recovers to more than half of a normal level. For another example, the model in which the columella is attached between the intermediate region is shown in Figure 6 (b). Analysis result is shown in Figure 4. In this case, the value of the maximum displacement is 2.79 nm which is about 56% of the healthy subject. This means that hearing ability recovers to about half of the normal level.

By comparing the stapes displacement of the tympanoplasty model with the healthy type, it becomes possible to estimate the restoration ratio, not only in the type Ⅲ operation but also in the type Ⅳ operation. The validity of our proposal has been verified by harmonic vibration analysis.

4 INFLUENCE OF COLUMELLA VOLUME ON SOUND CONDUCTION

4.1 Geometric model

As a part of the optimum design, the correlation of hearing restoration effect and the columella volume has been examined in the type Ⅲ operation model [10]. In this research, the type Ⅳ operation models in which the columella volume is different are examined. The standard model is shown in Figure 7 (a). The additional models are twice and three times the volume of the standard model as shown in Figure 7 (b) and (c). In the analysis of these models, only the size of the columella width was changed.



(a) Standard model (b) Twice volume model (c) 3 times volume model

Figure 7: Geometric models varying in the volume of columella

4.2 Finite element analysis results

In this research, harmonic vibration analysis was performed as a dynamic analysis using the finite element method. The material data of Figure 7 are the same as Table 1 and the boundary conditions of this model are the same as the conditions described in section 3.3. Figure 8 shows the harmonic vibration analysis results of three models varying in the volume of the columella.

In Figure 8, the longitudinal axis shows the average displacement of the stapes basal plane, and the lateral axis represents the frequency. The solid line is the result for the standard model.

The dashed line is the result for the model where the volume of the columella is 2 times that of the standard model. The dotted line is the result for the model where the volume of the columella is 3 times that of the standard model. Figure 8 shows that the displacement of the stapes base plane increases gradually with an increase in the volume of the columella. By increasing the columella volume, it is possible to more firmly connect the columella on the malleus or stapes. Therefore, it appears to improve the transfer efficiency of sound.

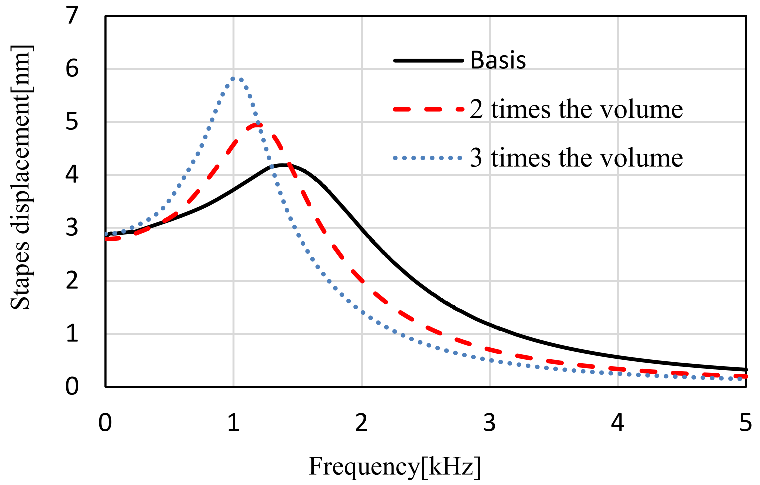


Figure 8: Comparison of frequency response graphs

5 OTOSCLEROSIS MODEL AND EVALUATION OF HEARING ABILITY

5.1 Geometric model for otosclerosis

(a) Annular ligament hardening model (b) Artificial stapes model

Figure 9: Otosclerosis and its operation model

In otosclerosis, abnormal bone growth occurs around the stapes. For this reason, stapes usually stiffen and conductive hearing loss occurs as one symptom of otosclerosis. In order to reproduce the severe hardening of stapes, a model where the Young’s modulus of a whole annular ligament increased 100 times that of the healthy subject, 0.65 MPa, was made [2]. This model is shown in 9 (a).

In otosclerosis operation, the upper horseshoe part of the stiffened stapes is removed, and a small open window is made in the stapes base plate. Then, a substitute stapes is attached to the hole. As a substitute for the stapes, a Teflon piston was used in this analysis. The operation model using the Teflon piston is shown in Figure 9 (b).

5.2 Materia data

The Teflon piston ⑮ is composed of the main part and the joint. Teflon (PTFE) was used for the main body, and cartilage for the joint. Material data for Teflon piston ⑮ is shown in Table 2. Material data for the joint is the same as the value of ⑪ in Table1. Other materials ① ~⑭ are shown in Figure 3 and Table 1.

Table 2: Material data of artificial stapes

Anatomical parts' name	Young's Modulus [MPa]	Density [kg/m^3]	Poisson's ratio
⑩Stapedial annular ligament	65	2,500	0.3
⑮Teflon piston (PTFE)	500	2,165	0.46

5.3 Finite element analysis results

In this research, harmonic vibration analysis was performed as a dynamic analysis using the finite element method. Boundary conditions in the analysis models of Figure 9 are the same as the conditions described in section 3.3. Figure 10 shows the harmonic vibration analysis results. The solid line is the result for a healthy subject. The dashed line is the annular ligament hardening model in which the Young's modulus was increased to 100 times that of the healthy subject due to otosclerosis. The dotted line is the result of the operation model using an artificial Teflon piston as the stapes.

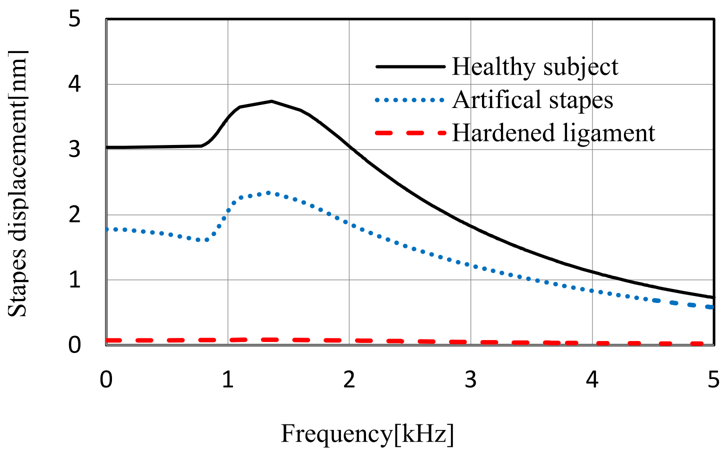


Figure 10: Comparison of frequency response graphs

The operation model is about 2.26 nm in the displacement of the substitute stapes at the resonant frequency. The maximum displacement is lower by about 38% in comparison with the healthy subject (3.66 nanometer, in this model). However, this is greater than the result in which the Young's modulus of the annular ligament is the strongly hardened model.

5.4 Evaluation of hearing ability

In the medical field, the audiogram is made by precise audiometry, and the degree of improvement of hearing ability is evaluated in pre- and post-operation. The audiogram is the record of the value of hearing level or minimum audible threshold at every frequency in the hearing test. A calculation formula which is able to obtain hearing level from the stapes displacement using the finite element analysis was devised as follows.

$$L_{HL} = 20\log_{10}(\delta_0/\delta) \tag{2}$$

In equation (2), L_{HL} is the hearing level that shows the minimum audible threshold ($L_{HL} = 0$ [dB], for a healthy subject). δ_0 is the stapes displacement for a healthy subject and δ is the stapes displacement for a patient. The degree of hearing amelioration can be evaluated quantitatively by this formula. In this study, our proposed method is applied to operation models for otosclerosis, and its validity is discussed.

The hearing level which was calculated by equation (2) using the results of Figure 10 is shown in Table 3. Results of Moriyama et al. [9] in Table 3 show the mean value of audiometry results which was carried out in pre- and post-operation for 16 otosclerosis patients. Figure 11 shows the audiogram made by using the result of Table 3. Our pre-operation results correspond to the result of the annular ligament hardening model (dashed line) and our post-operation results correspond to the result of the operation model using an artificial Teflon piston (solid line).

Table 3: Hearing level and improvement rate

Frequency [Hz]	Measured result by Moriyama et al. [dB]		Our analysis result [dB]	
	Pre-operation	Post-operation	Pre-operation	Post-operation
250	48	15	35.3	8.09
500	39	8	35.4	8.55
1000	35	6	35.7	7.78
2000	25	5	34.6	6.61
4000	25	6	31.4	3.71
Mean hearing level	33.5	6.25	35.35	7.68
Improvement rate	27.25		27.67	

A decrease in hearing acuity in lower frequencies appears for the result of Moriyama et al. On the other hand, this phenomenon is not seen for the model in which the Young's modulus of an annular ligament increased. Therefore, this model has not exactly reproduced the otosclerosis. Though some differences are observed in our analytical results and experimental results of Moriyama et al., both results are quite similar. It seems possible to reproduce the audiogram using our method.

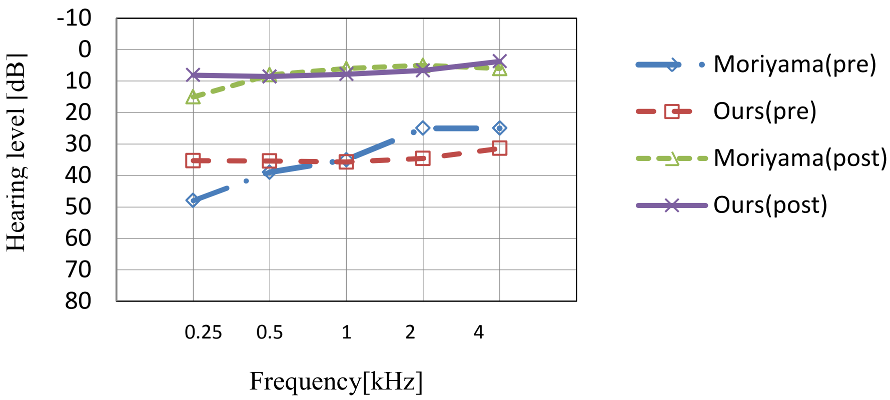


Figure 11: Comparison of audiogram

The mean hearing level of Table 3 is a value calculated according to the following equation used in audiometry.

$$L_{MHL} = \frac{H_{500} + 2H_{1000} + H_{2000}}{4} \tag{3}$$

In equation (3), L_{MHL} is mean hearing level, H_{500} is minimum audible threshold at 500Hz, H_{1000} is minimum audible threshold at 1000Hz and H_{2000} is minimum audible threshold at 2000Hz. If the difference in mean hearing level between pre- and post-operation is regarded as improvement rate, our result becomes almost 100% of the experimental result.

The hearing restoration effect can be estimated quantitatively prior to the operation using our proposal method. Through this study, the optimization of the reconstruction of the middle ear using the columella becomes possible.

6 CONCLUSIONS

We have proposed that the hearing restoration effect can be estimated by comparison of the displacement of the stapes basal plane quantitatively prior to the operation. In order to verify this proposal, various types of operation models, especially the type Ⅳ operation model in addition to the type Ⅲ operation model, were analyzed using harmonic vibration analysis and compared with a healthy subject. Furthermore, the production method of the audiogram, that is, the record of minimum audible threshold using finite element analytical results was applied to the type Ⅳ operation model. As a result, the following knowledge was obtained.

(1) We have analyzed the effect of mounting positions of the columella in type Ⅲ and type Ⅳ operation models. It was shown that the maximum hearing restoration rate in type Ⅲ and type Ⅳ operation models was about 94% and 60% respectively. With the type IV operation, it is more difficult to improve hearing ability than with the type III operation.

(2) In the type Ⅳ operation model, the correlation of hearing restoration effect and the columella volume was examined. It was clarified that the hearing restoration effect increased with an increase in the columella volume as shown in the type Ⅲ operation model too.
(3) The calculation formula which is able to produce an audiogram from stapes displacement was devised and applied to the artificial stapes model for otosclerosis treatment which is considered as a kind of type Ⅳ operation. The degree of hearing amelioration can be evaluated quantitatively by this method for not only the type Ⅲ model but also the type Ⅳ model .
(4) Through this study, the optimization of reconstruction of the middle ear using the columella becomes possible. Finally, the efficacy of predicting the hearing restoration effect prior to an operation was verified.

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